K111669

DEC 15 2011

Section 7- 510(k) Summary of Safety and Effectiveness

7.1 Statement	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92
7.2 Submitter/ Date	Insulet Corporation 9 Oak Park Drive Bedford, MA. 01730 Date Prepared: December 14, 2011
7.3 Company Contact	Susan Finneran Senior Director, Clinical and Regulatory Affairs 9 Oak Park Drive Bedford, MA. 781-457-5234
7.4 Device Name	**Proprietary Name:** OmniPod® Insulin Management System **Common Name:** OmniPod System **Classification Name:** Infusion pump, 21CFR 880.5725
7.5 Predicate Legally Marketed Devices	The Insulet OmniPod Diabetes Management System that is the subject of this submission is substantially equivalent to the IXL-ii System that was cleared via K042972.
7.6 Device Description	The OmniPod® Insulin Management System is intended for subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin and for the quantitative measurement of glucose in fresh whole

Capillary blood (in vitro).

The OmniPod Insulin Management system consists of two main components:

- The Personal Diabetes Manager (PDM)
- The OmniPod (Pod)

The Personal Diabetes Manager (PDM) handles all processes for the operation of the OmniPod System. The display uses full text language to prompt the user through the set up process. It is also utilized to initialize and program the Pod with the user's custom based insulin profile, to check the pod status, and initiate a bolus dose of insulin. Using the PDM the user can also make temporary changes to the insulin delivery profile. After set-up and initiation, the Pod will run independently of the PDM.

The PDM device incorporates the Freestyle glucose meter. The PDM receives blood glucose readings that are measured using the Freestyle blood glucose meter via an internal serial interface. The blood glucose data is stored and can be displayed by the PDM. The integrated glucose test meter is intended to be used with Abbott Freestyle test strips.

The Pod is the disposable component of the system. The Pod is intended to be filled with rapid acting insulin U-100. The brands of insulin that can be utilized with the Pod are as follows: Novolog®/NovoRapid®, Humalog®, or Apidra®.

Once the Pod has been filled with a minimum volume of insulin the tubing in the pump is primed. Once primed the user is instructed to remove the adhesive backing and place the Pod adhesive side down on the body. Once in place, the needle punctures the injection site and the cannula is deployed for insulin delivery.

7.7 **Indications for Use**

The OmniPod Insulin Management System is intended for subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin and for the quantitative measurement of glucose in fresh whole capillary blood (in vitro) from the finger.

The glucose measurements should not be used for the diagnosis of or screening for diabetes. The PDM glucose meter is intended for single-patient use and should not be shared.

Abbott FreeStyle test strips are used with the built in FreeStyle meter for the quantitative measurement of blood glucose in fresh whole capillary blood from the finger, upper arm and palm. Abbott FreeStyle Control Solutions are used to verify that the meter and test strips are working together properly and that the test is performed correctly.

7.8 Summary of changes to the predicate device

Several changes were made to the OmniPod System since it was originally cleared via K042792. Following is a summary of the changes that were made to the PDM component of the system since it was originally cleared via K042792.

- Replacement of the LCD with a color version.
- A modified device shell and combined function of the Home and Power On/Off buttons into one button.
- Addition of USB port
- Removal of two "hard" buttons – Blood Glucose Records button and Food Database button.

Changes to the Software User Interface:

- New home screen.
- Customized BG tags
- New status screen.
- New confirmation screen

- Update to labeling to indicate that the OmniPod System may be used with Abbott Freestyle test strips.

7.9 Summary of supporting data

The intent of this premarket notification was to submit data to support that the glucose meter that is incorporated into the device can be used with the GDH-FAD glucose test strips that have been recently cleared by Abbott Diabetes Care. This premarket notification also includes verification data to support the changes to the device since it was cleared via K042792.

Table 7.1 provides a summary of the tested that was completed to verify performance of the GDH-FAD strip with the OmniPod System and to support changes that were made to the OmniPod System since it was initially cleared.

Table 7.1 Summary of Supporting Verification/ Clinical Testing

Test Report Reference	Summary of Testing
TP/TR09-217	Verification of meter functionality was completed in accordance with ISO 15917:2003.
TP/TR10-067	75 subjects at two sites were evaluated. Whole capillary blood was collected and measured by the subject and by a trained user. The results were also compared to a glucose reference sample measured with the YSI 2300 Stat Plus device. Subject's were also asked to rate the use of the device

TP/TR10-326	Cleaning/ Disinfection testing of the meter was completed to demonstrate that the device could be disinfected appropriately and remain functional after multiple cycles.
TP/TR08-078 TP/TR08-233 TP/TR09-21	Software verification, unit testing, code reviews.
TP/TR07-273	EMC testing to demonstrate compliance to 60601-1-2
TP/TR07-176 TP/TR07-177 TP/TR07-178 TP/TR07-179	Hardware verification testing

The data presented above demonstrates that the device is safe and effective and is substantially equivalent to the predicate device cleared via K042792.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Susan Finneran
Senior Director Clinical and Regulatory Affairs
Insulet Corporation
9 Oak Park Drive
Bedford, Massachusetts 01730

DEC 15 2011

Re: K111669
Trade/Device Name: OmniPod® Insulin Management System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG
Dated: December 9, 2011
Received: December 12, 2011

Dear Ms. Finneran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices /ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem /default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):_K111669

Device Name:_OmniPod® Insulin Management System

Indications For Use:

The OmniPod Insulin Management System is intended for subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin and for the quantitative measurement of glucose in fresh whole capillary blood (in vitro) from the finger.

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Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kathleen E. Applegate for LCC

(Division Sign-Off)

Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K111669